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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,579	05/06/1998	ULF LANDEGREN	1209-122P	6255

7590 02/25/2004

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EXAMINER	
AKHAVAN, RAMIN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant 02/23/04 EA

Office Action Summary	Application No.	Applicant(s)	
	09/029,579	LANDEGREN, ULF	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, 10 and 12* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/05/2004 has been entered. The claims pending are 7, 9, 10 and 12.

Response to Amendment

See the rejection below (§ 112, first ¶) with respect to amendments made to claim 7. In sum, the amendment has introduced new matter in the form of a negative limitation not literally supported by the specification. Applicant contends that amendment finds support throughout in the specification (e.g., p. 4, ll. 14-15; p. 5, ll. 24-36). However, the specification does not contain *any* support at the designated cites, or anywhere else, with respect to the negative limitation, "[W]herein said composition does not contain said target nucleic acid."

Response to Arguments

Applicant's arguments, see Remarks, filed 02/05/2004, with respect to previously made rejections under 35 U.S.C. § 112 have been fully considered and are persuasive. The rejections of claim 12 have been withdrawn.

Applicant's arguments with respect to the rejection made under § 102(b) have been fully considered but they are not persuasive. See rejection below under Claim Rejections – 35 USC § 102.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Claims 7, 9, 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

Claim 7 recites, "[W]herein said composition does not contain said target nucleic acid." There is no literal support in the specification for this limitation. As such, claim 7 by amendment, introduces *impermissible* New Matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 7, 9-10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The claims are drawn to a composition (padlock probe) with a functional limitation where target nucleic acids are "directly inhibited". The specification does not specifically define this term, but does make references to binding of the padlock probe to target nucleic acids resulting in inhibition of expression (e.g. Spec. pp. 4, 7). However, as written the claim is vague and indefinite. It would be remedial to incorporate appropriate specification-supported language in the claim (e.g. "directly inhibit gene expression").

In addition claim 12 recites that the padlock probe comprises a "non-natural nucleic acid". The specification does not specifically define "non-natural", but does indicate that, "the effects of the padlock probes may be accentuated by at least partially building probes of *non-natural* nucleic acids...". (Emphasis added, Spec. p. 7, ll. 5-7). As written the claim is vague and indefinite. For example, molecules of DNA that are synthesized would be "non-natural", or a stretch of DNA from a natural host (e.g. mouse) that is subcloned and propagated in bacteria could be deemed as non-natural. Therefore, the claim's metes and bounds as written are indefinite.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7, 9-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson et al. (Science, 1994; 265:2085-8; hereinafter Nilsson).

The claims are drawn to a composition for targeting double stranded nucleic acids comprising a pharmaceutically acceptable carrier, a padlock probe and the composition does not contain said target nucleic acids.

Before discussing the current grounds for rejection, it would beneficial to future prosecution of this application to address applicant's remarks viz., previously made rejections. With respect to the previously made rejection applying Nilsson, Applicant asserts that Nilsson does not teach what is claimed. Applicant's contention is partly based the assertion that Nilsson does not teach a pharmaceutically acceptable carrier (i.e. the ligation buffer) or only teaches washing the padlock probe in said buffer, and that the ligation buffer Nilsson teaches *would* comprise target nucleic acids.

First, with regard to the contention that Nilsson only teaches washing in a buffer; this assertion is incorrect because Nilsson *does* teach that the probe is in the ligation buffer, even if for a limited time (Nilsson, at 2087, Fig. 4). Therefore, the probe and the buffer would constitute the composition claimed – the probe in a pharmaceutically acceptable carrier.

Applicant's second contention is with regard to the buffer itself, which applicant asserts does not constitute a pharmaceutically acceptable carrier. Applicant acknowledges that the additional references cited (Rajagopalan et al. USP 5,162,109; Shelley USP 5,505,961; Mills USP 5,132,118; and Rapaport USP 5,227,371) provide evidence that individual components of the ligation buffer are acceptable carriers, but asserts that not one of the references cited teaches that the ligation buffer is intrinsically a pharmaceutically acceptable carrier. However, if Nilsson is silent about an intrinsic characteristic (i.e. pharmaceutically acceptable) with regard to the ligation buffer, then the gap may be filled with extrinsic evidence, where the additional references make clear that each component of the ligation buffer is a pharmaceutically acceptable carrier.

Where the claims are drawn to a composition, absent evidence to the contrary, a characteristic attributed to individual components would be maintained if such components were to be combined. Put another way, the quality of the components comprising the ligation buffer are substantially and significantly the same, thus there is no evidence to suggest that the ligation buffer would not inhere the characteristic of being a pharmaceutically acceptable carrier.

However, it would be correct to point out that the ligation buffer would contain the padlock probe and target nucleic acids, thus the foregoing discussion with respect to the ligation buffer would only support a rejection where the ligation buffer did not contain target nucleic acids.

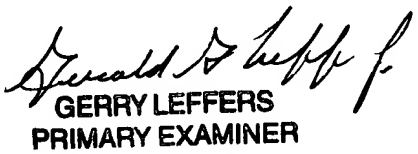
As to the current grounds for rejection, Nilsson teaches a composition comprising a padlock probe, where at least for a moment in time the composition does not contain any target nucleic acids, and where the composition comprises a pharmaceutically acceptable. For example, Nilsson teaches that the padlock probe is added to a hybridization mix (see p. 2087, Fig. 4, middle of figure description), which means that the probe was contained in a solution that contained water. As the claim language is "open" (i.e. "comprising" a pharmaceutically acceptable carrier), then the buffer comprising the padlock probe as taught by Nilsson would contain water, which is certainly a pharmaceutically acceptable carrier. Furthermore, there would not be any target nucleic acids in this solution prior to the hybridization step. Therefore Nilsson anticipates the rejected claims.

Conclusion

No claims are allowed. All references cited herein have been previously provided to applicant, thus will not be forwarded with this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:30-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



GERRY LEFFERS
PRIMARY EXAMINER